This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-75(canceled).

76(new). An assay method for the determination of holo-Transcobalamin II (holo-TCII) in a body fluid sample, comprising:

contacting a sample of a body fluid with an immobilized or immobilizable cobalamin or an analogue or fragment thereof which selectively binds the apo-forms of TCII and haptocorrin (HC) in said sample over the holo-forms thereof,

separating said selectively bound TCII from said sample or rendering said selectively bound TCII unable to bind to a specific binding ligand for TCII or holo-TCII,

contacting the non-bound TCII with a specific binding ligand for TCII or holo-TCII to bind said holo-TCII to form a ligand bound fraction and a non-ligand bound fraction, and

measuring the TCII content of said ligand bound fraction to determine the quantity of holo-TCII in the body sample being assayed.

77(new). An assay method as claimed in claim 76 wherein said specific binding ligand is a ligand selected from the group consisting of a polyclonal antibody, a monoclonal antibody, and an antibody fragment.

78(new). An assay method as claimed in claim 76 wherein said specific binding ligand exhibits a high degree of selectivity and specificity towards TCII and exhibits low affinity towards other transcobalamin proteins, in either apo or holo form, or any other cobalamin-binding protein.

79(new). An assay method as claimed in claim 76 wherein said specific binding ligand binds holo-TCII with an affinity constant of at least 10^9M^{-1}.

80(new). An assay method as claimed in claim 76 wherein said specific binding ligand binds holo-TCII with an affinity constant of greater than $10^{11}M^{-1}$.

81(new). An assay method as claimed in claim 76 wherein the degree of cross-reactivity of said specific binding ligand with HC is less than 0.1%.

82(new). An assay method as claimed in claim 76 wherein said sample which is contacted with the immobilized cobalamin or analogue or fragment thereof is further contacted with a solid phase support having immobilized thereon said specific binding ligand and to which is bound a labelled ligand recognizing the same binding sites on the immobilized specific binding ligand as holo-TCII, whereby holo-TCII in said sample competes with said bound labelled ligand for said binding sites such that after equilibration of the system there is a directly proportional relationship between the amount of labelled ligand displaced from said solid phase support and detectable in solution and the amount of holo-TCII present in the original sample; said labelled ligand being detected directly or indirectly as the amount of labelled ligand bound or not bound to said solid phase support as appropriate.

83(new). An assay method as claimed in claim 76 wherein said sample which is contacted with the immobilised cobalamin or analogue or fragment thereof is further contacted with a solid phase support having holo-TCII immobilised thereon and with a labeled non-immobilised holo-TCII specific binding ligand, whereby free holo-TCII in the sample and immobilised holo-TCII compete for binding to the labelled non-immobilised ligand; and determination of the labelled ligand bound to the solid phase support or remaining in solution allows determination of the holo-TCII concentration.

84(new). An assay method as claimed in claim 76 wherein said sample which is contacted with the immobilised cobalamin or analogue or fragment thereof is further contacted with labeled holo-TCII and an immobilised ligand therefor whereby labelled and non-labeled holo-TCII compete for binding to the immobilised ligand and after equilibrium is reached, the amount of labeled holo-TCII bound to the immobilised ligand is indirectly proportional to the amount of holo-TCII in the sample.

85(new). An assay method as claimed in claim 76 wherein said body fluid sample is a sample selected from the group consisting of seminal fluid, cerebro-spinal fluid, amniotic fluid and a blood derived sample.

86(new). An assay as claimed in claim 85 wherein said blood derived sample is serum or plasma.

87(new). An assay method as claimed in claim 76 wherein said bound fraction is separated from said unbound fraction by precipitation, centrifugation, filtration or chromatographic methods.

88(new). An assay method as claimed in claim 76 wherein said ligand is labelled with a signal forming label which may be determined by luminescence, chemiluminescence, colorimetric assessment, fluorescence, radioactivity or by enzymic activity.

89(new). An assay method as claimed in claim 76 in which assay calibration is effected using a holo-TCII standard.

90(new). An assay as claimed in claim 89 wherein said standard is human, native or recombinant holo-TCII.

Claims 71-72(canceled).